REMARKS

This case contains claims 1-2, 5-18, and 20-23 with the entry of this Amendment. Claims 1 and 18 have been amended to better claim the subject matter which Applicants regard as the invention. Specifically, amended claim 1 recites the limitations of claims 3-4. Thus, claims 3-4 have been canceled without prejudice. Amended claim 18 recites the limitations of claim 19. Accordingly, claim 19 has been canceled without prejudice. Claim 5 has been amended to correct the dependency. Accordingly, none of the amendments made herein constitutes addition of new matter.

Rejections under 35 U.S.C. § 103:

Claims 1-23 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Glenn *et al.* (US Patent No. 5,980,898). Applicants respectfully traverse this rejection.

The Patent Office alleges that Glenn *et al.* teaches a transcutaneous immunization formulation comprising antigen and an adjuvant applied to unbroken skin and the antigen may be derived from a virus.

Without acquiescing to this aspect of the rejection and in the interest of advancing the prosecution of this application, claims 1 and 18 (two independent claims) have been amended. Amended claim 1 specifically recites that the compositions for inducing an immune response are antigenic particles of certain size (50-200 nm in diameter) and do not require addition of an adjuvant. Amended claim 18 specifies that the composition comprise attenuated live virus particles without an adjuvant.

In contrast, the system disclosed by Glenn *et al.* uses an adjuvant, preferably an ADP-ribosylating exotoxin. In addition, as pointed out by the examiner, Glenn *et al.* does not teach the method of inducing an immune response where the composition lacks an adjuvant nor does Glenn *et al.* teach the size of the antigenic particles.

Applicants emphasize the fact that the claimed invention is the results of their discovery that an efficient immunization can be carried out by relatively large antigenic particles, i.e., live viruses or particles from 50-200 nm in diameter, by a transcutaneous route without the aid of an

adjuvant. Glenn *et al.* does not teach nor suggest the invention as now claimed. The focus of the Glenn *et al.* reference is to develop a method of increasing the efficiency of the immune response when a given antigen was administered transcutaneously. Accordingly, various adjuvants were disclosed in Glenn *et al.* to achieve this goal. The mention of the viruses in the cited reference appears to be as a general source of the antigenic material not as an intact virus particle or antigenic particle of a specified size (50-200 nm in diameter) as is the case in the present application.

Based on the foregoing, it is submitted that the claimed invention is not *prima facie* obvious over Glenn *et al.* Withdrawal of the rejection under 35 U.S.C. § 103 is respectfully requested.

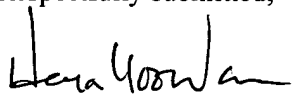
Conclusion

In view of the foregoing amendments and arguments, it is submitted that this case is in condition for allowance and passage to issuance is respectfully requested.

If there are any outstanding issues related to patentability, the courtesy of a telephone interview is requested, and the Examiner is invited to call to arrange a mutually convenient time.

It is believed that the present submission does not require the payment of any fees. If this is incorrect, however, please charge any fee due under the foregoing Rules to Deposit Account No. 07-1969.

Respectfully submitted,



Heeja Yoo-Warren
Reg. No. 45,495

GREENLEE, WINNER AND SULLIVAN, P.C.
5370 Manhattan Circle, Suite 201
Boulder, CO 80303
Telephone: (303) 499-8080
Facsimile: (303) 499-8089
E-mail: winner@greenwin.com
Attorney docket No. 25-01
nnr: August 8, 2002

1. (Twice amended) A method for inducing an immune response comprising the step of applying to the unbroken surface of the skin a composition [consisting essentially of] comprising antigenic particles and a pharmaceutically acceptable carrier[.] wherein said antigenic particles are of diameter from about 50 to 200 nm and said composition does not contain an adjuvant.

5. (Once amended) The method of claim [4] 1 wherein the antigenic particles are about 100 nm in diameter.

18. (Once amended) A method for inducing an immune response comprising the step of applying to the unbroken surface of the skin a composition [consisting essentially of] comprising live virus particles and a pharmaceutically acceptable carrier[.] wherein said composition does not contain an adjuvant and said live virus particles are attenuated virus particles.